

In response to the Office Action of February 26, 2004, please amend the application as follows:

IN THE CLAIMS

Claims 1-24 (Cancelled).

25. (Withdrawn) Process for preparing the pharmaceutical composition according to claim 1, comprising operating in pre-sterile environment, steriley filtrating 5 through 0,22 µm filters, collecting the filtrate in sterile environment and distributing it in sterile vials.

26. (Withdrawn) Process for preparing the pharmaceutical composition according to claim 2, operating in pre-sterile environment, steriley filtrating through 0,22 µm filters, collecting the filtrate in sterile environment and distributing it in sterile 10 vials.

27. (Withdrawn) Spray unit containing a composition according to claim 1, and equipped with a multidose pump, absolute filter for the aspiration air, and an auto-blocking mechanism of the actuator.

28. (Withdrawn) Spray unit containing a composition according to claim 2, 15 and equipped with a multidose pump, absolute filter for the aspiration air, and an auto-blocking mechanism of the actuator.

29. (Withdrawn) Spray unit according to claim 27, wherein the vial is of glass.

30. (Withdrawn) Spray unit according to claim 27, wherein the vial is of plastic.

20 Claims 31-37 (Cancelled).

38. (New) A pharmaceutical composition stable for at least 18 months at room temperature which comprises a therapeutically effective amount of a peptide or of a pharmaceutically acceptable derivative thereof selected from the group consisting of derivatives and analogues of oxytocin and vasopressin and the salts thereof and further 5 containing a buffer in aqueous solution, wherein the composition has a pH between 3.5 and 6, wherein the composition is free from preservatives selected from the group consisting of adsorption inhibitors which inhibit adsorption of the peptide onto a container's walls and degradation inhibitors selected from the group consisting of antioxidants and antimicrobial additives.

10 39. (New) A pharmaceutical composition stable for at least 18 months at room temperature consisting of a therapeutically effective amount of a peptide or of a pharmaceutically acceptable derivative thereof selected from the group consisting of derivatives and analogues of oxytocin and vasopressin and the salts thereof and of a buffer in aqueous solution, wherein the composition has a pH comprised between 3.5 and 6, 15 wherein the composition is free from preservatives selected from the group consisting of adsorption inhibitors which inhibit adsorption of the peptide onto container's walls and degradation inhibitors selected from the group consisting of antioxidants and antimicrobial inhibitors.

40. (New) The stable pharmaceutical composition according to claim 38, 20 wherein the peptide is selected from the group consisting of the analogues of vasopressin, and the salts thereof.

41. (New) The pharmaceutical composition according to claim 39, wherein the peptide is selected from the group consisting of the analogues of vasopressin, and the salts thereof.

42. (New) The pharmaceutical composition according to claim 40, wherein the analogue of vasopressin contains a mercaptopropanoyl radical.

43. (New) The pharmaceutical composition according to claim 41, wherein the analogue of vasopressin contains a mercaptopropanoyl radical.

5 44. (New) The pharmaceutical composition according to claim 42, wherein the analogue of vasopressin is desmopressin acetate hydrate.

45. (New) The pharmaceutical composition according to claim 43, wherein the analogue of vasopressin is desmopressin acetate hydrate.

10 46. (New) The pharmaceutical composition according to claim 38, wherein the buffer is selected from the group consisting of citric acid/disodium phosphate dihydrate and citric acid/trisodium citrate dihydrate.

47. (New) The pharmaceutical composition according to claim 39, wherein the buffer is selected from the group consisting of citric acid/disodium phosphate dihydrate and citric acid/trisodium citrate dihydrate.

15 48. (New) The pharmaceutical composition according to claim 38, containing an agent for controlling the osmolarity.

49. (New) The pharmaceutical composition according to claim 39, further containing an agent for controlling the osmolarity.

50. (New) The pharmaceutical composition according to claim 48, wherein the 20 agent for controlling the osmolarity is sodium chloride.

51. (New) The pharmaceutical composition according to claim 49 wherein the agent for controlling the osmolarity is sodium chloride.

52. (New) The pharmaceutical composition according to claim 38, containing at least 0.02 mg of desmopressin, at least 3 mg of the buffer, and an amount of an agent for

controlling the osmolarity such that the osmolarity is kept at the physiologic values of the human plasma, and 1 ml of purified water.

53. (New) The pharmaceutical composition according to claim 39, containing at least 0.02 mg of desmopressin, and containing at least 3 mg of the buffer, and further 5 containing an amount of an agent for controlling the osmolarity such that the osmolarity is kept at the physiologic values of the human plasma, in 1 ml of purified water.

54. (New) The pharmaceutical composition according to claim 46, containing from 3 to 6 mg of citric acid/disodium phosphate dihydrate buffer, or from 5 to 11 mg of citric acid/trisodium citrate dihydrate buffer.

10 55. (New) The pharmaceutical composition according to claim 52, containing from 0.02 to 0.15 mg of desmopressin, from 1 to 2.5 mg of citric acid monohydrate, from 2 to 5 mg of disodium phosphate dihydrate, 1 ml of water and an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.

15 56. (New) The pharmaceutical composition according to claim 55, containing 0.1 mg of desmopressin, 1.7 mg of citric acid monohydrate, 3 mg of disodium phosphate dihydrate, 1 ml of water and an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.

20 57. (New) The pharmaceutical composition according to claim 47, containing from 3 to 6 mg of citric acid/disodium phosphate dihydrate buffer, or from 5 to 11 mg of citric acid/trisodium citrate dihydrate buffer.

58. (New) The pharmaceutical composition according to claim 53, containing from 0.02 to 0.15 mg of desmopressin, from 1 to 2.5 mg of citric acid monohydrate, from 2 to 5 mg of disodium phosphate dihydrate, 1 ml of water and further an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.

59. (New) The pharmaceutical composition according to claim 55, containing 0.1 mg of desmopressin, and containing 1.7 mg of citric acid monohydrate, 3 mg of disodium phosphate dihydrate, in 1 ml of water and further an amount of sodium chloride such that the osmolarity is kept at the physiologic values of the human plasma.

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